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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,972	05/11/2001	BARRY ROSS MATTHEWS	017227/0171	7954

7590 03/18/2005

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,972

Applicant(s)

MATTHEWS ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/14/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination, remarks and amendment filed 12/14/04.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 12/14/04 has been entered.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Matthews et al. (WO 95/34595).

Matthews teaches a compound and a composition comprising said compound. The compound is a polyamidoamine or polylysine dendrimer that has a plurality of terminal cationic or anionic containing moiety (abstract, pages 2-6 and claims 1-40 and figure 1). The composition is administered orally, rectally, topically, transdermally, parenterally and nasally to a patient in need thereof to treat infections caused by toxins. An example of such an infection is HIV. See page 7, line 6 to page 9 line 14 and claims 37-40. The teachings anticipate the claims.

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Applicant appears to draw a distinction between antiviral activity and inhibition of toxic material or substance by stating that antiviral activity refers to the inhibition of the replication of the virus and not to the replication of any toxic material/substance originating from the virus. Applicants further state that toxin is not an infectious agent like a virus.

Upon reference to applicant's specification, page 9, lines 4-10, and figure 1 it appears that "toxic materials or substances" embrace the actual viruses themselves as well as toxic substances released from the viruses. Amended claim 1 recites that the toxic material or substance is selected from the group consisting of (i) "toxins and toxic peptides of biological origin and (ii) toxins and toxic peptides released during bacterial, protozoal or fungal infection." Therefore, when interpreting the claims in view of applicant's specification, the Examiner respectfully submits that the claims even as amended appear to read on method of inhibiting viral activity.

Applicants argue that claim 1 as amended bears no reference to "toxins and toxic peptides released during viral infection."

3. Applicants' arguments filed 12/14/04 have been fully considered but they are not persuasive because amended claim 1 still recites toxic material or substance to be selected from the group consisting of (i) "toxins and toxic peptides of biological origin and (ii) toxins and toxic peptides released during bacterial, protozoal or fungal infection."

Double Patenting

4. Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36, 38 and 39 of U.S. Patent No. 6,190,650. An

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claims because the examined claim is either anticipated by or would have been obvious over the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

In this case, claim 38 of the reference prophylactically or therapeutically treats viral infection in human or non-human with the composition of claim 1. Claim 1 of the reference encompasses claim 7 of the application. The application for the most part recites a method of inhibiting toxic material where the toxic material is a viral infection (claims 1 and 12) and the method comprises administering an effective amount of a dendrimer to a patient in need thereof. The issued patent for the most part teaches a dendrimer composition and a method for administering the composition to treat the same conditions or infections that are caused by toxins. Treating or treatment encompasses inhibiting. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of the issued patent. One having ordinary skill in the art would have been motivated to administer the composition of the issued patent to a patient in need thereof with the expectation that the composition would treat or inhibit activity of the toxic material or substance released from viral infection.

Applicant argues that the amended claim recites “toxins and toxic peptides released during bacterial, protozoal or viral infection” and that the amended claim excludes toxins and toxic peptides released during viral infection.

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5. Applicants' arguments filed 12/14/04 have been fully considered but they are not persuasive.

“Toxins and toxic peptides of biological origin” as recited under (i) of the amended claims can/may be released during viral infection since they of biological origin. And upon reference to applicant’s specification, page 9, lines 4-10, and figure 1 it appears that “toxic materials or substances” embrace the actual viruses themselves as well as toxic substances released from the viruses. Therefore, when interpreting the claims in view of applicant’s specification, the Examiner respectfully submits that the claims even as amended appear to read toxins and toxic peptides released during viral infection since claim 1 requires the toxic material to be one of (i) “toxins and toxic peptides of biological origin and (ii) toxins and toxic peptides released during bacterial, protozoal or fungal infection.” The scope of the issued patent is encompassed within the scope of the claimed invention.

A terminal disclaimer will overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name.